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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,963	05/29/2001	Bruce Hammock	23070138000	9763

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EXAMINER

GUO, LYNDIA T

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/867,963	<b>Applicant(s)</b> HAMMOCK ET AL.	
	<b>Examiner</b> Lynda T Guo	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status of the Application***

Applicant's petition was granted and made of record on February 14, 2002 (Paper No. 5).

Claims 1-10 are currently pending in the present application.

A search of available literature has not yielded any evidence to support the linkage linoleic acid diols to pre-eclampsia, eclampsia or pregnancy-induced hypertension.

### ***Oath/Declaration***

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The first page of the declaration states the citizenship of Jiang Zheng as China but the citizenship changed to the United States on the second page of the declaration.

### ***Specification***

2. The disclosure is objected to because of the following informalities: Several punctuation errors were found. On page 2, line 8, parentheses are needed for the citation; line 27 of the same page is missing a closing parenthesis after the last citation. Page 25, line 18, end parenthesis

after citation should be deleted; line 26 of the same page needs end parenthesis before the period.

Lastly, page 31, line 4, a period (---) is missing at the end of the paragraph.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-10 are drawn to a method of identifying a patient with a disorder; however, no method steps were disclosed in the Claims. Said Claims only specify that the method is an immunoassay. Though immunoassays are commonplace to one of ordinary skill in the art, there are a myriad of immunoassays available. Thus, without specified steps, said Claims are rendered vague and indefinite. Standard method steps in an immunoassay include contacting, determining and correlating.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bursten et al. (USPN 5,780,237) in view of Jude et al., in further view of Street et al.  
Claim 1 is drawn to a method of diagnosing a disorder by assaying levels of linoleic acid diol. Dependent Claims 2-10 further limit the assay in that the diol assayed is leukotoxindiol; disorders desired to diagnose is selected from the group consisting of hypertension, adult respiratory distress syndrome (ARDS), cardiovascular disease and lipid metabolism defect; assay is an immunoassay, particularly competitive or non-competitive ELISA; and the sample assayed is blood or urine.  
Bursten discloses a diagnostic assay for ARDS by measuring levels of unsaturated fatty acids in a body fluid (e.g. serum, plasma, urine and others). Bursten teaches that there are several assay methods, including immunoassays (which encompasses competitive and non-competitive assays as both types are well recognized in the art, as Applicant recites on page 26 in "Immunological Binding Assays", along with a list of references). (See Abstract; Column 3, lines 12-17, 26-32;

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and Column 12, Claims 1, 3 and 4.) Bursten's teaching differs from Applicant's in that Bursten's method assays linoleic acid whereas Applicant assays for linoleic acid diol or its respective glucuronide conjugate. However, Jude et al. and Street et al. teach that linoleic acid diol, glucuronides and leukotoxin diol have been isolated from urine of patients suffering from generalized peroxisomal disorders, respectively, as well as the serum of patients with severe burns (See Jude, age 294, left column, lines 1-2, right column, paragraph 1 and Street, page 3507, Abstract and first paragraph.) Street et al. further teaches that measurement of these compounds could be useful in the diagnosis of peroxisomal disorders (a group of lipid metabolic disorders). (See last paragraph of Abstract.) It is, thus, immaterial whether the antibodies generated for the immunoassay are for detecting linoleic acid or its diol since both the acid and its diol are both known in the art as being present in urine or serum samples of patients with various recited diseases. Results for either assay would generate similar results. Therefore, it would have been obvious to one of ordinary skill in the art to modify Bursten's diagnostic assay to detect linoleic acid diols.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lynda T Guo  
Patent Examiner  
October 28, 2002



RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200